

**3. 510(k) Summary**

Sponsor: Synthes (USA)  
1302 Wrights Lane East  
West Chester, PA 19380

Contact: Angela Silvestri  
Synthes (USA)  
1230 Wilson Drive  
West Chester, PA 19380  
(484) 356-9728

Device Name: Norian CRS Bone Cement

Device Classification: 21 CFR 882.5300 – Methyl methacrylate for cranioplasty

Device Description: Norian CRS Bone Cement is an injectable, moldable, and biocompatible bone cement. The Reactants Pack contains sterile powder (calcium phosphate) and a syringe that contains sterile solution (dilute sodium phosphate). The Reactants Pack is designed to be placed in a reusable mixer where the 2 components are mixed together to form a smooth, viscous paste that remains injectable for approximately 5 minutes at 18°-23°C / 64°- 73°F. At body temperature (37°C / 98.6°F), Norian CRS Cement begins to harden after 2 minutes and sets in approximately 10 minutes. Norian CRS Cement is slowly resorbed and replaced by bone over a period of years. This material is provided sterile and is for single use only.

Indications for use: Norian CRS Bone Cement is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas) such as burr hole voids and other craniofacial defects, with a surface area no larger than 25cm<sup>2</sup>.

Norian CRS Bone Cement is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Predicate Device Norian CRS Bone Cement K973789

Substantial Equivalence Determination This device is equivalent to the predicate in terms of material composition, physical properties and performance characteristics.



APR 13 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Synthes (USA)  
c/o Ms. Angel Silvestri  
Group Manager, Regulatory Affairs  
1230 Wilson Drive  
West Chester, Pennsylvania 19380

Re: K060445  
Trade/Device Name: Norian CRS Bone Cement  
Regulation Number: 21 CFR 882.5300  
Regulation Name: Methyl methacrylate for cranioplasty  
Regulatory Class: II  
Product Code: GXP  
Dated: February 16, 2006  
Received: February 23, 2006

Dear Ms. Silvestri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Angel Silvestri

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2. Indications for Use Statement

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510(k) Number (if known): \_\_\_\_\_

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Contraindications:

Norian CRS Bone Cement is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K060445